UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ALLISON OTTESEN, et al.,

Plaintiffs,

v.

HI-TECH PHARMACEUTICALS, INC.,

Defendant.

Case No. 19-cv-07271-JST

ORDER GRANTING PLAINTIFFS' MOTION TO LIFT STAY; ORDER SETTING CASE MANAGEMENT CONFERENCE

Re: ECF No. 66

This case concerns the alleged use of DMHA[1] in supplements manufactured, distributed, and sold by Defendant Hi-Tech Pharmaceuticals, Inc. On November 20, 2020, the Court stayed the case on primary jurisdiction grounds, "pending a determination by the FDA regarding the classification of DMHA." ECF No. 56 at 6.

At the time, the Food and Drug Administration ("FDA") had "issued warning letters and . . . a constituent update stating, in unequivocal terms, that 'DMHA is either "a new dietary ingredient" for which the FDA has not received the required New Dietary Ingredient notification or that it is an unsafe food additive. The FDA considers dietary supplements containing DMHA to be adulterated.'" *Id.* at 4 (quoting ECF No. 49 at 5). However:

> [T]he FDA [had] itself acknowledged that its position on DMHA is not final. In moving to dismiss a related case before a district court in the District of Columbia, the agency explained that the statements in its warning letter to Hi-Tech regarding products containing DMHA "are not 'final and binding' on the Agency or [Hi-Tech], but rather remain 'tentative and interlocutory in nature.'" ECF No. 47-4 at 13 (citation omitted). The FDA also stated that the warning letter "did not mark the consummation of the FDA's decisionmaking." *Id.*

[1] The complaint uses "DMHA" as shorthand for the substance also called, variously, 2-Aminoisehptane HCI, 1,5-DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine. ECF No. 1 at 8-9.

Id. at 4–5 (alteration in original). Because the FDA "expressed further interest in the classification of DMHA by indicating that its decision-making is still ongoing," the Court could not "conclude that the positions expressed in the FDA's warning letters and its constituent update resolve the question at hand." *Id.* at 5.

On August 15, 2023, Plaintiffs moved to lift the stay, arguing that the FDA "provided clarity on its position" based on a website page last updated on March 6, 2023. ECF No. 66 at 3. Plaintiffs quoted the following language:

> The pre-2020 actions listed below [including Hi-Tech Pharmaceuticals, Inc.] reflect the Agency's position as of April 2019 when the FDA had concluded that DMHA was either an adulterated "new dietary ingredient" or an unsafe food additive. After further research and consideration, FDA concluded that DMHA is an unsafe food additive, as explained above. The Agency still considers dietary supplements containing DMHA to be adulterated.

FDA, *DMHA in Dietary Supplements* (Mar. 6, 2023), https://www.fda.gov/food/dietary-supplement-ingredient-directory/dmha-dietary-supplements [https://perma.cc/BN87-K7JX]). The FDA website also states that the "FDA considers DMHA to be a substance that does not meet the statutory definition of a dietary ingredient and is an unsafe food additive. Accordingly, we consider dietary supplements containing DMHA to be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act)." *Id.*

Hi-Tech correctly observes that Plaintiffs failed to notify the Court with seven days of the FDA's March 6, 2023 website update, which indicates either that Plaintiffs did not view the update as a final determination by the FDA or that they violated the Court's order to "notify the Court within seven days of a final determination by the FDA." ECF No. 56 at 6. In addition, the legislative history of the Dietary Supplement Health and Education Act, which is one of the bases of Plaintiffs' claims, indicates that if the FDA seeks "to declare a dietary supplement adulterated," it "would publish a notice in the Federal Register proposing to [do so] and setting forth the basis for their position that a substantial and unreasonable risk of illness or injury is presented." S. Rep. No. 103-410, at 35 (1994) (quoted with approval in *Rosas v. Hi-Tech Pharms.*, No. CV 20-00433-DOC-DFM, 2020 WL 5361878, at *4 (C.D. Cal. July 29, 2020)). That process has not occurred in this case.

Nonetheless, the FDA website states that the agency has "concluded that DMHA is an unsafe food additive," and that it "considers dietary supplements containing DMHA to be adulterated." *DMHA in Dietary Supplements*. Nothing about this language appears tentative, nor—unlike the last time this question came before the Court—is there any indication in the record that the FDA's "decision-making is still ongoing." ECF No. 56 at 5. In the absence of any such evidence, the Court concludes that there no longer is a basis for a stay. This case is now more similarly situated to *Reid v. Johnson & Johnson, Inc.*, in which the Ninth Circuit affirmed denial of a motion to stay on primary jurisdiction grounds where the FDA had issued warning letters regarding "No Trans Fat" statements and "there [was] no indication that the FDA [was] contemplating authorizing [such] statements" or "signs [that the FDA was] backing away from its determination" regarding the question at issue. 780 F.3d 952, 966–67 & n.9 (9th Cir. 2015).

Plaintiffs' motion to lift the stay is granted. The parties shall appear for a case management conference on November 7, 2023 at 2:00 p.m., and file a joint case management statement seven days prior.

IT IS SO ORDERED.

Dated: October 17, 2023

JON S. TIGAR
United States District Judge